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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,736	08/02/1999	ELISABETH WOLPERT	000500-182	3510

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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07/28/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 09/319,736	Applicant(s) WOLPERT ET AL.	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 148-158, 160, 161, 163 and 164 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 151, 160, 161, 164 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1643

DETAILED ACTION

Claims 150 and 158 have been amended. Claims 148-158, 160, 161, 163 and 164 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 157, 160, 161 and 164 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the following reasons of record. Claim 158 is also rejected for the same reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 157 is drawn to a composition comprising cells isolated according to the method of claim 148. Claim 158 is drawn to a process which requires the T cells that selectively recognize cells showing impaired cellular peptide processing for MHC presentation, and thus are T cells which be produced from the process of claim 155. Claim 160 is drawn to cells isolated according to the method of claim 148, antigens or epitopes expressed by said cells. Claim 161 is drawn to a composition comprising immunological effector cells isolated according to the method of claim 155 and claim 164 is drawn to a composition comprising effector cells isolated by the method of claim 163. It is noted that claims 157 and 160 are dependent upon the cell isolated by the method of claim 148. The products of claims 157, 160, 161 and 164 lack adequate written description, because the specification cannot adequately describe cells which have yet to be isolated. It logically follows that if a product itself is not adequately described, the method of using said product cannot be adequately described.

Art Unit: 1643

Applicant again argues that the claims are product by process claims which meet the limitations of 112, first paragraph. This is unpersuasive because the isolation of the CTL as the final product are not adequately described because the endogenous epitopes associated with impaired cellular peptide processing cannot be controlled or predicted or described by the process. Thus the CTL which recognize such epitopes cannot be adequately described and compositions claims reliant on the identity of the CTL.

Applicant argues that the PTO issues claims to antibodies which are deemed adequately described without making such antibodies. This is not persuasive. The technology of making antibodies is mature and only fully described proteins can be relied upon. Applicant further argues that the form of a product by process claim is often the best means of claiming a desired product. This has been considered but not found persuasive. Even for product by process claims, the resulting product must be adequately described, and this is not the case for the instant invention for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 157, 160 are rejected under 35 U.S.C. 102(b) as being anticipated by Holcombe et al (Journal of Experimental Medicine, 1995, Vol. 181, pp. 1433-1443).

Claim 157 is drawn to a composition comprising cells isolated according to the method of claim 148. Claim 160 is drawn in part to antigens or epitopes expressed by said cells in a pharmaceutically acceptable additive.

Holcombe et al disclose that the RMA-S cell line is a T lymphoma cell line that lacks the TAP-2 subunit of the peptide antigen transporter (page 1435, second column, lines 1-3 under “Results”. Holcombe et al disclose that the s-RMA cell line expresses the TL antigen independent of TAP transport (abstract). Holcombe et al disclose a composition comprising the TL antigen in a complex with B2m in PBS which meets the imitation of claim 160 requiring a pharmaceutically acceptable additive.

Art Unit: 1643

The disclosure of Holcombe et al meets the limitation of the claims because said claims are product by process claims, and therefore a product which has the same characteristics as a product obtained by carrying out the method steps of claim 148 will anticipate the claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 161 and 164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holcombe et al (Journal of Experimental Medicine, 1995, Vol. 181, pp. 1433-1443).

Claim 161 is drawn to a composition comprising immunological effector cells isolated by the method of claim 155. Claim 164 is drawn to a composition comprising isolated immunological effector cells that selectively recognize cells showing impaired cellular peptide processing for MHC presentation.

Holcombe et al teach that although peptide-specific TL-antigen restricted cells have not been reported, allorecognition of TL antigen by CTL has recently been demonstrated (page 1434, first column, lines 8-12).

It would have been prima facie obvious to isolate the specific CTL recognizing the TL antigen. One of skill in the art would have been motivated to do so by the teachings of Holcombe et al regarding the existence of said CTL by allorecognition..

All other rejections and objections as set forth or maintained in a previous Office action are withdrawn

Claims 148-156 and 163 are allowed.

Claims 157, 158, 160, 161 and 164 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643